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EXAMINER	
YU, MELANIE J	
ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/681,639	SHI, QINWEI	
	Examiner	Art Unit	
	MELANIE YU	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *3,4,8,9,14-19,22,23 and 27-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-7,10-13,20-26 and 33-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/2 and 10/7*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 5 August 2009 has been considered and entered.

Information Disclosure Statement

2. The reference indicated with a strike through in the information disclosure statement filed 7 October 2009 has not been considered because the reference is a foreign patent document and a copy has not been submitted as required by 37 CFR § 1.97.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 2, 5, 6, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naka et al. (US 6,001,307) in view of Hodges et al. (US 6,612,111).

Naka et al. teach a platform comprising a reagent film for detecting at least one component in a low volume liquid sample (membrane channel is analytical section, 3,

col. 11, lines 34-42 and liquid sample flows through the membrane, which is the reagent film, col. 11, lines 44-47; small amount of sample, col. 2, lines 42-47), the reagent film providing a channel through which the liquid sample can flow by capillary action (reagent film is in analytical section, 3, col. 11, lines 34-42 and liquid sample flows through the film, which is the reagent film, col. 11, lines 44-47) while reactions take place determinative of at least one component in the sample (reagent film impregnated with a reagent, col. 11, lines 15-17 and indicate the presence of a component in the sample, col. 11, lines 44-47);

the platform formed with sample application means and having top and bottom layers (top and bottom layers, 5a and 5b, Fig. 6A and 6B; col. 15, lines 12-15; sample application means formed in the platform, 4, Fig. 6A and 6B; col. 33-34) with surfaces to enclose and position the reagent film (top and bottom layers, 5a and 5b, Fig. 6A and 6B; col. 15, lines 12-15; film held between the top and bottom layers, col. 15, lines 26-27), each layer having a top and bottom surface formed so that the bottom surface of the top layer and the top surface of the bottom layer are brought into fixed face to face contact so that the layers enclose and hold the film into place (reagent film, 7, is held between the top and bottom layers, col. 15, lines 26-27) and form a platform flow channel upstream of the reagent film and downstream of the sample application means (drawing channel, 2a, is upstream of the reagent film membrane, 7, and downstream from the sample application means, 4, Fig. 6A and 6B; col. 15, lines 32-38), and including at least one indent in at least one of the surfaces (funnel shape, 4, is indent, Fig. 6A and 6B; col. 15, lines 33-34); and

the formed platform flow channel is in fluid communication with the reagent film to permit the liquid sample to flow in a continuous pathway from the upstream sample application means through the platform flow channel and then to an edge of an upstream end of the reagent film towards the distal end of the reagent film (col. 15, lines 25-38).

Naka et al. differ from the instant claims by failing to teach that the reagent film is a dry porous membrane that allows the liquid sample to flow by capillary action and the top and bottom layers are hydrophilic.

Hodges et al. teach a platform comprising a reagent film that is a dry porous membrane for detection at least one component in a sample (porous membrane in analysis chamber, col. 9, lines 29-35; analysis chamber with reagents capable of reacting with analytes in the sample, col. 9, lines 40-46; color indicator for analyte, col. 9, lines 56-61), the membrane providing a membrane channel through which the liquid sample can flow by capillary action (sample flows through analysis chamber by capillary action, col. 9, lines 29-46) while reactions take place determinative of at least one component in the sample (col. 9, lines 47-63);

the platform formed with sample application means (needle used to draw sample into device, col. 9, lines 11-15) and having top and bottom layers with hydrophilic surfaces to enclose and position the membranes (walls of analysis chamber coated with hydrophilic material, col. 9, lines 35-40), each layer having a top and bottom surface formed so that the bottom surface of the top layer and the top surface of the bottom layer may be brought into face to face contact so that the layers enclose and hold the

membrane in place (porous material is held between the two layers, and therefore enclosed by the face to face contact of the device, col. 9, lines 29-40; top and bottom layers, 24, hold porous material, not shown, in analysis chamber, 20, Fig. 2, therefore the top and bottom layers hold the porous material in place) and form a platform flow channel upstream of the membrane and downstream of the sample application means (platform flow channel, 14, is upstream from membrane, contained in analysis chamber, 20, and downstream of sample application means, left of 60, Fig. 2; col. 7, line 21-col. 8, line 63), in order to provide a device that draws a blood sample that is inexpensive, disposable and simple enough for home or hospital bedside use.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include on the top and bottom layers of Naka et al., a hydrophilic coating on the top surface of the bottom layer and the bottom surface of the top layer and the reagent film being a dry porous membrane through which the liquid sample can flow by capillary action as taught by Hodges et al., in order to encourage the flow of liquid sample into and through the sample analysis chamber.

With respect to claims 5 and 10, Naka et al. teach a window in the top layer for observing the results of a reaction that takes place in the membrane (col. 11, lines 3-7).

4. Claims 20, 24, 25, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naka et al. (US 6,001,307) in view of Hodges et al. (US 6,612,111) further in view of McCroskey et al. (US 5,271,895).

Naka et al. teach a platform comprising a detection membrane upstream from a reagent film and overlapping the reagent film for filtering substantially all of the red

blood cells from the sample (col. 11, lines 14-24) and a mobile labeled detection reagent that reacts with one of the components in the sample and moves downstream (sample contacted with label and then moved into analytical section containing immobilized capture agents, wherein the labeled sample binds to immobilized capture agents, col. 30, lines 31-42),

the reagent film detecting at least one component in a low volume liquid sample (membrane channel is analytical section, 3, col. 11, lines 34-42 and liquid sample flows through the membrane, which is the reagent film, col. 11, lines 44-47; small amount of sample, col. 2, lines 42-47), the reagent film providing a channel through which the liquid sample can flow by capillary action (reagent film is in analytical section, 3, col. 11, lines 34-42 and liquid sample flows through the film, which is the reagent film, col. 11, lines 44-47) while reactions take place determinative of at least one component in the sample (reagent film impregnated with a reagent, col. 11, lines 15-17 and indicate the presence of a component in the sample, col. 11, lines 44-47);

the platform formed with sample application means and having top and bottom layers (top and bottom layers, 5a and 5b, Fig. 6A and 6B; col. 15, lines 12-15; sample application means formed in the platform, 4, Fig. 6A and 6B; col. 33-34) with surfaces to enclose and position the reagent film (top and bottom layers, 5a and 5b, Fig. 6A and 6B; col. 15, lines 12-15; film held between the top and bottom layers, col. 15, lines 26-27), each layer having a top and bottom surface formed so that the bottom surface of the top layer and the top surface of the bottom layer are brought into fixed face to face contact so that the layers enclose and hold the film into place (reagent film, 7, is held between

the top and bottom layers, col. 15, lines 26-27) and form a platform flow channel upstream of the reagent film and downstream of the sample application means (drawing channel, 2a, is upstream of the reagent film membrane, 7, and downstream from the sample application means, 4, Fig. 6A and 6B; col. 15, lines 32-38), and including at least one indent in at least one of the surfaces (funnel shape, 4, is indent, Fig. 6A and 6B; col. 15, lines 33-34); and

the formed platform flow channel is in fluid communication with the reagent film to permit the liquid sample to flow in a continuous pathway from the upstream sample application means through the platform flow channel and then to an edge of an upstream end of the reagent film towards the distal end of the reagent film (col. 15, lines 25-38).

Naka et al. differ from the instant claims by failing to teach that the reagent film is a dry porous membrane that allows the liquid sample to flow by capillary action, the top and bottom layers are hydrophilic and the detection membrane containing a mobile labeled detecting reagent which will react with one of the components and slightly overlapping the upstream end of the reagent film.

Hodges et al. teach a platform comprising a reagent film that is a dry porous membrane for detection at least one component in a sample (porous membrane in analysis chamber, col. 9, lines 29-35; analysis chamber with reagents capable of reacting with analytes in the sample, col. 9, lines 40-46; color indicator for analyte, col. 9, lines 56-61), the membrane providing a membrane channel through which the liquid sample can flow by capillary action (sample flows through analysis chamber by capillary

action, col. 9, lines 29-46) while reactions take place determinative of at least one component in the sample (col. 9, lines 47-63);

the platform formed with sample application means (needle used to draw sample into device, col. 9, lines 11-15) and having top and bottom layers with hydrophilic surfaces to enclose and position the membranes (walls of analysis chamber coated with hydrophilic material, col. 9, lines 35-40), each layer having a top and bottom surface formed so that the bottom surface of the top layer and the top surface of the bottom layer may be brought into face to face contact so that the layers enclose and hold the membrane in place (porous material is held between the two layers, and therefore enclosed by the face to face contact of the device, col. 9, lines 29-40; top and bottom layers, 24, hold porous material, not shown, in analysis chamber, 20, Fig. 2, therefore the top and bottom layers hold the porous material in place) and form a platform flow channel upstream of the membrane and downstream of the sample application means (platform flow channel, 14, is upstream from membrane, contained in analysis chamber, 20, and downstream of sample application means, left of 60, Fig. 2; col. 7, line 21-col. 8, line 63), in order to provide a device that draws a blood sample that is inexpensive, disposable and simple enough for home or hospital bedside use.

McCroskey et al. teach a detection membrane that filters red blood cells out of blood samples (filter medium, 41, Fig. 4; filter layer is detection membrane and is upstream from the capture membrane so colored red blood cells do not interfere with optical detection, col. 8, lines 39-53) and contains labeled reagents for the analyte (reagent for detection may be located in filter means, col. 3, lines 4-8) slightly

overlapping a capture membrane (reagent detection layer, 43, col. 8, lines 39-47), in order to provide detection of the presence or concentration of analyte in a sample.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include on the top and bottom layers of Naka et al., a hydrophilic coating on the top surface of the bottom layer and the bottom surface of the top layer and the reagent film being a dry porous membrane through which the liquid sample can flow by capillary action as taught by Hodges et al., in order to encourage the flow of liquid sample into and through the sample analysis chamber. It would have further been obvious to one having ordinary skill in the art at the time the invention was made to include in the filtration layer of Naka et al. in view of Hodges et al., a labeled reagent specific for analyte and slightly overlapping a capture membrane having a concentration line for analyte as taught by McCorskey et al., in order to provide sufficient removal of substances from a sample that may interfere with detection.

With respect to claims 24, 34 and 35, Naka et al. teach a window in the top layer for observing the results of a reaction that takes place in the membrane (col. 11, lines 3-7) and may be polyester (col. 29, lines 29-35).

With respect to claim 33, McCorskey et al. teach the detection membrane being a glass fibre (glass fleece, col. 6, lines 59-61) and the capture membrane being a nitrocellulose membrane (col. 6, lines 62-65).

5. Claims 2, 7 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naka et al. (US 6,001,307) in view of Hodges et al. (US 6,612,111), as applied to claims 1 and 6, further in view of McCorskey et al. (US 5,271,895), as applied to claim

20, and further in view of Zimmer et al. (WO 99/29429). Since the WO document was not published in English, the citations herein refer to the English translation of this document, US 7,238,534. A direct translation of the WO document will be provided upon applicant's request.

Naka et al. in view of Hodges et al. further in view of McCorskey et al. teach a platform flow channel having an indent in the top surface of the bottom layer (4, Fig. 6b), but differ from the instant claims by failing to specifically teach an indent in the bottom surface of the top layer.

Zimmer et al. teach an indent for receiving a sample in either the top surface of a bottom layer (notch 5 is present in the bottom layer, 7, of the device, Fig. 6) or bottom surface of a top layer (notch, 5, Fig. 2) of a platform comprising top and bottom layers (top layer 1 and bottom layer 7, form platform, Fig. 2; col. 6, lines 23-35), in order to provide a sample application zone for penetration of a sample liquid.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the indent for receiving a sample in Naka et al. in view of Hodges et al. further in view of McCorskey et al., in either the top surface of the bottom layer or bottom surface of the top layer as taught by Zimmer et al. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent sample application notch and since the same expected sample application effect would have been obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the desired location of sample application.

6. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naka et al. (US 6,001,307) in view of Hodges et al. (US 6,612,111), as applied to claim 6, and Freitag et al. (US 6,214,629).

Naka et al. in view of Hodges et al. teach a device comprising reagents for analyte detection, but fail to teach the analyte being Troponin I.

Freitag et al. teach reagents for the detection of Troponin I in a chromatographic assay (col. 9, line 63-col. 10, line 21), in order to provide detection of cardiac analytes.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Naka et al. in view of Hodges et al., reagents in a porous material for the detection of Troponin I in a blood sample as taught by Freitag et al., in order to provide diagnosis for the cause of chest pain and to determine a cardiac event.

7. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Naka et al. (US 6,001,307) in view of Hodges et al. (US 6,612,111) in view of McCorskey et al. (US 5,271,895), as applied to claim 20, and Freitag et al. (US 6,214,629).

Naka et al. in view of Hodges et al. further in view of McCorskey et al. teach a device comprising reagents for analyte detection, but fail to teach the analyte being Troponin I.

Freitag et al. teach reagents for the detection of Troponin I in a chromatographic assay (col. 9, line 63-col. 10, line 21), in order to provide detection of cardiac analytes.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Naka et al. in view of Hodges et

al. further in view of McCorskey et al., reagents in a porous material for the detection of Troponin I in a blood sample as taught by Freitag et al., in order to provide diagnosis for the cause of chest pain and to determine a cardiac event.

8. Claims 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naka et al. (US 6,001,307) in view of Hodges et al. (US 6,612,111), as applied to claims 1 and 6, and Deng (US 6,740,293).

Naka et al. in view of Hodges et al. teach a device comprising a top surface and bottom player in fixed face to face contact to form a flow channel, but fail to teach open areas to inhibit flow into space between the top and bottom layers and protrusions in the top layer that mate with indents in the bottom layer.

Deng teaches a device comprising platform with a top layer (13, Fig. 7) and a bottom layer (12, Fig. 7), wherein the top layer and bottom layer comprise a flow channel having a test strip (col. 6, line 59-col. 7, line 3) wherein the top and bottom layers have open areas, which inhibit flow from the platform flow channel into space between the surfaces of the top and bottom layers (flow is limited to the porous strip, col. 9, lines 19-28; space is between side wall of 12 and test strip 19, which prevents flow between 12 and 13 when they are sealed; openings are created to prevent flow from creeping into handle section, which is between top and bottom layers, col. 7, lines 44-54) and the top surface of the lower layer comprising cylindrical pillars (11a, Fig. 8) that register with cylindrical indents (11b, Fig. 8; col. 6, lines 14-22), in order to provide secure snapping and prevent leaking between the top and bottom layers.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the platform of Naka et al. in view of Hodges et al., cylindrical pillars that register with indents and open areas that inhibit flow of the sample between the top and bottom layers as taught by Deng, in order to provide sufficient sealing and prevent leaking outside of the device.

Deng fails to teach the protrusions being rectangular. However, it would have been obvious to one having ordinary skill to provide a different shape to perform the same function of snapping the top and bottom layers together. In re Dailey et al. 149 USPQ 47 (C.C.P.A. 1966).

Response to Arguments

9. Applicant's arguments with respect to claims 1, 2, 5, 7, 10-13, 20, 21, 24-26 and 33-39 have been considered but are moot in view of the new ground(s) of rejection. The previous rejections of the claims have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of applicant's amendment requiring the platform channel to flow both upstream of the detection membrane and downstream of the sample application means.

Conclusion

No claims are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Yu/
Primary Examiner, Art Unit 1641